

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

AIS GMBH AACHEN INNOVATIVE
SOLUTIONS, et al.,

Plaintiffs,

v.

THORATEC LLC,

Defendant.

Case No. 16-mc-80094-EJD (SVK)

**ORDER ON THORATEC'S MOTION
TO RETAIN CONFIDENTIALITY
DESIGNATIONS**

Re: Dkt. No. 75

Before the Court is the motion of Defendant Thoratec LLC ("Thoratec") for an order retaining the "HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY" designation for the HeartMate PHP device produced pursuant to the Protective Order in this action. Dkt. 75. The Court held a hearing on January 12, 2021. For the reasons that follow, the Court **GRANTS** Thoratec's motion.

I. BACKGROUND

A. Litigation History

Thoratec competes with Abiomed Inc. ("Abiomed"), the parent company of Petitioners AIS GmbH Aachen Innovative Solutions ("AIS") and Abiomed Europe GmbH ("Abiomed Europe") (collectively, AIS and Abiomed Europe are referred to as "Petitioners"), in the field of heart pump technology. *See* Dkt. 75-4, paras. 8-9. In October 2015, Petitioners filed patent infringement complaints in Germany against Thoratec and a related company, Thoratec Europe ("German Actions"). Dkt. 1, paras. 16-17. These actions asserted that Thoratec's HeartMate PHP heart pump infringed certain of Petitioners' European patents. *Id.*

On May 4, 2016, Petitioners filed an *ex parte* application for discovery in aid of foreign litigation pursuant to 28 U.S.C. § 1782 in this Court. Dkt. 1. Petitioners' memorandum of law in support of their section 1782 application represented as follows:

Any confidential information obtained can be maintained as confidential upon submission to the German courts. German court files are not publicly accessible and Germany has mechanisms to protect the confidentiality of evidence presented in their courts. (*See* Decl. ¶ 11.) Accordingly, if used in the German Actions, there is minimal risk of disclosure of Thoratec’s confidential information (if any) to the public.

Dkt. 2 at 14.

The Court granted Petitioners’ section 1782 application in July 2016. Dkt. 16. A flurry of motion practice followed, and in April 2017, the Court ordered Thoratec to produce three HeartMate PHP devices, with three each of any associated hardware or accessories, and a console to control the devices (hereinafter collectively referred to as “Device”). Dkt. 49 at 6. The Court also evaluated competing proposed protective orders from both sides, and, on April 28, 2017, entered the version proffered by Abiomed. *Id.* at 4; Dkt. 51. Immediately thereafter, Thoratec launched a series of appeals, all of which were, by March 2019, unsuccessful. Dkt. 69, 72.

With this Court’s discovery orders (Dkt. 16, 49) and Protective Order (Dkt. 51) in place, the Parties turned to production of the Device for use in the German Actions. As part of this process, Abiomed challenged the confidentiality designation of the Device pursuant to section 6.2 of the Protective Order.¹ Dkt. 75-1, Ex. D. Two of the grounds cited by Abiomed in its challenge were prior sales of and public viewing of the HeartMate PHP devices. *Id.* at 20. Following negotiations (Dkt. 75-1 at 2, para. 6), on August 13, 2019, the Parties reached the following agreement (“Agreement”) regarding the Device:

The HeartMate PHP pumps and console qualify as “highly Confidential – Attorneys’ Eyes Only” under the Protective Order.

Dkt. 75-1, Ex. E. The Parties also negotiated which individuals would have access to the Device, in accordance with the Protective Order. *Id.*, paras. 2-7.

The Parties then proceeded with the German Actions, culminating in a hearing in Dusseldorf District Court in May 2020. Dkt. 79 at 3. At that hearing, Thoratec presented part of the Device referred to as the canula. Dkt. 75-3, para. 4; Dkt. 79-27, para. 5; Dkt. 81-9, para. 4.

¹ The Protective Order is examined more fully in section I.B. below.

Final judgment was issued in the German Actions on June 30, 2020, and the judgments are currently on appeal. Dkt. 75-3, para. 9. It is the German appellate proceeding that Abiomed cites as the reason for its need to dissolve the confidentiality protections for the Device. Dkt. 79 at 4. In support of its position, Abiomed predominantly argues that Thoratec's disclosure of the Device in the German hearing obviates the need for any further protection under the Protective Order. Dkt. 79 at 6-7. The Parties' disagreement on this point led Thoratec to bring the present motion for an order retaining the "Highly Confidential – Attorneys' Eyes Only" designation for the Device. Dkt. 75. Abiomed opposes the motion and asks the Court to dissolve the Protective Order or, at a minimum, re-designate the HeartMate PHP as merely "Confidential." Dkt. 79 at 19.

B. The Protective Order

The Protective Order defines "CONFIDENTIAL" information or items as information or things that qualify for protection under Federal Rule of Civil Procedure 26(c).² Dkt. 51, para. 2.9. "HIGHLY CONFIDENTIAL–ATTORNEYS' EYES ONLY" ("AEO") material is defined as "extremely sensitive 'Confidential Information or Items,' disclosure of which to another Party or Non-Party would create a substantial risk of serious harm that could not be avoided through less restrictive means." *Id.*, para. 2.16. A wider array of party-affiliated personnel have access to the opposing party's "CONFIDENTIAL" information than the opposing party's AEO information. *Compare id.*, paras. 7.2 and 7.3. The Protective Order was entered in connection with patent litigation in Germany and will remain in place during the appeals of those cases. *See id.*, paras. 1, 2.15, 4. Within 60 days after the final disposition of the German Actions, all protected material must be returned. *Id.*, para. 14.

The Protective Order sets forth the procedure for designating materials and testimony in pretrial or trial proceedings. *Id.*, para. 5.2. It also sets forth how a party or non-party challenges a confidentiality designation. A designation may be challenged at any time, and a challenge is not

² Federal Rule of Civil Procedure 26(c) states: "The court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense."

waived simply because it is not raised promptly. *Id.*, para. 6.1. The challenging party must initiate a meet and confer process by serving a notice that specifies that the challenge to confidentiality is made in accordance with paragraph 6 of the Protective Order. *Id.*, para. 6.2. The parties must meet and confer within 14 days of the date of service of notice. *Id.* The party who designated the challenged material must file motion to retain confidentiality within 21 days of initial notice of challenge or within 14 days of agreeing that meet and confer will not resolve their dispute, whichever is earlier. *Id.*, para. 6.3. Failure to make such a motion will automatically waive the confidentiality designations for each challenged designation. *Id.* The Designating Party bears burden of persuasion on a motion to retain confidentiality. *Id.* In addition, the Challenging Party may file a motion challenging the designation at any time if there is good cause, but must also comply with the meet and confer requirements of paragraph 6.2. *Id.*

II. LEGAL STANDARD

As a general rule, “the public is permitted access to litigation documents and information produced during discovery.” *In re Roman Catholic Archbishop of Portland in Oregon*, 661 F.3d 417, 424 (9th Cir. 2011) (citation omitted). Nevertheless, a court “may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense.” *Id.* (quoting Fed. R. Civ. P. 26(c)(1)). “The party opposing disclosure has the burden of proving ‘good cause,’ which requires a showing ‘that specific prejudice or harm will result’ if the protective order is not granted.” *Id.* (citing *Foltz v. State Farm Mut. Auto. Ins. Co.*, 331 F.3d 1122, 1130 (9th Cir. 2003)).

Courts often make a finding of good cause before issuing a protective order, but “a court need not do so where ... the parties stipulate to such an order.” *In re Roman Catholic Archbishop*, 661 F.3d at 424. If a party challenges whether documents have been properly designated as confidential under a stipulated protective order, the party seeking to maintain confidentiality “has the burden of establishing that there is good cause to continue the protection of the discovery material.” *Id.*

A court considering a motion to retain confidentiality designations proceeds in two steps. First, the court must determine whether “particularized harm will result from disclosure of the

information to the public.” *Id.* (citation omitted). Second, “if the court concludes that such harm will result from disclosure of the discovery documents, then it must proceed to balance the public and private interests to decide whether maintaining a protective order is necessary.” *Id.* (internal quotation marks and citations omitted). The factors to be balanced are: (1) whether disclosure will violate any privacy interests; (2) whether the information is being sought for a legitimate purpose or for an improper purpose; (3) whether disclosure of the information will cause a party embarrassment; (4) whether confidentiality is being sought over information important to public health and safety; (5) whether the sharing of information among litigants will promote fairness and efficiency; (6) whether a party benefitting from the order of confidentiality is a public entity or official; and (7) whether the case involves issues important to the public. *Id.* (citing *Glenmede Trust Co. v. Thompson*, 56 F.3d 476, 483 (3d Cir. 1995)); *see also Economus v. City and County of San Francisco*, No. 18-cv-01071-HSG (DMR), 2019 WL 3842008, at *2 (N.D. Cal. Aug. 15, 2019).

III. DISCUSSION

A. Particularized Harm

The unique facts of this case do not fit squarely into the framework set forth in *In re Roman Catholic Archbishop* and *Glenmede Trust Co. v. Thompson*. Nevertheless, the Court begins its analysis with the question of whether there is good cause for maintaining confidentiality of the Device. Accordingly, the Court first asks whether “particularized harm” will result from disclosure of the Device?

Before the Court are the declarations of Janel Drews (Dkt. 74-6), Director, Finance Global Operations, for St. Jude Medical Business Services, Inc., and Keif Fitzgerald (Dkt. 75-4), Director Product Development at St. Jude Medical, Cardiology Division. Drews and Fitzgerald aver to the substantial number of years and millions of dollars invested by Thoratec in the development of the Device. Fitzgerald, who has worked on the Heartmate PHP Program for 10 years, further avers to the current, confidential features of the Device, including the precise configuration, design and engineering tolerances of its components; the type and grade of materials used in the components; and the strength, durability and performance of the components. Dkt. 75-4, para. 5. These

particular facts establish that if the Device were publicly disclosed today, Thoratec would suffer “particularized harm.”

Abiomed predominately argues that Thoratec has waived confidentiality protections for the Device by its presentation at the German hearing in May of 2020. The Court addresses that argument below. Abiomed also argues that Thoratec waived confidentiality by publications, patent disclosures, clinical trials, trade shows and sales. Dkt. 79 at 9-13. These arguments fail. First, as for sales and any public displays, Abiomed raised these issues in 2019 but subsequently agreed that the Device would be treated as AEO under the Protective Order.³ Dkt. 75-1, Exs. D and E. The publications, patent disclosures and sales cited by Abiomed in its Opposition once again predate the Protective Order and the Agreement and therefore do not factor into this Court’s analysis. Dkt. 79-2 through 79-19; 79-22; 79-23. The clinical trials are conducted under the cloak of confidentiality. Dkt. 75-6, paras. 3-4.

B. Other Considerations

Thus, having found that particularized harm will occur if the HeartMate PHP is disclosed, Ninth Circuit cases direct the Court to next consider the *Glenmede* public and private interest factors. *See In re Roman Catholic Archbishop*, 661 F.3d at 424. However, as noted above, the Court does not find these factors informative on the questions before the Court. The legal standard applicable to a motion for continuation of a protective order as articulated in *In re Roman Catholic Archbishop*, including the Ninth Circuit’s adoption of the *Glenmede* factors, was in the context of litigation pending in the United States. *See* 661 F.3d at 420. It is well-established that “the courts of this country recognize a general right to inspect and copy public records and documents, including judicial records and documents.” *Nixon v. Warner Communications, Inc.*, 435 U.S. 589, 597 (1978); *see also Kamakana v. City and County of Honolulu*, 447 F.3d 1172, 1178 (9th Cir. 2006). The Protective Order in this case, however, concerns materials produced for use in patent litigation in Germany. *See* Dkt. 51, paras. 2.15, 7.1. “Even recognizing that case law and policy concerns in the United States counsel against keeping court documents and files under

³ To the extent trade shows are encompassed in public displays, Abiomed’s evidence of disclosure of the Device at such events is inadmissible hearsay. Dkt. 79-21, para. 5,

1 seal, and against continuing to keep documents that led to a judgment under seal, that law and
 2 those policy concerns govern proceedings in this country’s courts—those same considerations
 3 might well be inapplicable elsewhere, especially in light of the secrecy of court files in Germany
 4 and other countries.” *In re Application of Heraeus Kulzer GmbH*, No. 3:09-CV-530 RM, 2015
 5 WL 5613156, at *2 (N.D. Ind. Sept. 22, 2015).

6 Here, the framework for the Parties’ negotiations that culminated in the Agreement and the
 7 subsequent production of the Device highlight the confidential nature of the German Actions. In
 8 support of its application for discovery under section 1782, Abiomed represented to the Court that
 9 “[a]ny confidential information obtained can be maintained confidential upon submission to the
 10 German courts.” Abiomed continued, “[a]ccordingly, if used in the German Actions, there is
 11 minimal risk of disclosure of Thoratec’s confidential information (if any) to the public.” Dkt. 2 at
 12 14. In addition, the parties expressly acknowledged in the Protective Order, which Abiomed
 13 drafted, that they “understand that German patent infringement proceedings are not public.” Dkt.
 14 51, para. 13.3.

15 Having emphasized the confidentiality of the German proceedings and the minimal risk of
 16 disclosure in its section 1782 application and the Protective Order, it is troubling to the Court that
 17 Abiomed now seeks to use that very proceeding to undo the AEO status of the Device. It does not
 18 appear to be disputed that the German hearing itself is not a confidential proceeding. Dkt. 75-3,
 19 paras. 4-7; Dkt. 79-27, para. 6. Nor is it disputed that members of the public were not present at
 20 the hearing. *Id.* The Parties’ descriptions of the nature and extent of Thoratec’s presentation of
 21 the Device, set forth by declarations of German counsel for each side, are carefully drawn and,
 22 with one notable exception addressed below, do not directly contradict each other. Thoratec’s
 23 counsel attests that:

- 24
- 25 • During the May 26, 2020 oral hearing, counsel for Thoratec briefly displayed the cannula
- 26 component of the HeartMate PHP device for less than one minute. The cannula was
- 27 shown at a distance of about 15 feet.
- 28 • Thoratec offered to allow the Court to inspect a component of the HeartMate PHP device,
- specifically, the cannula, but the Court declined the offer.
- Thoratec did not offer to allow the Court to inspect the full HeartMate PHP device or any

other components of the device.

Dkt. 75-3, paras. 4-7; Dkt. 81-9, para. 4.

Abiomed's German counsel counters in relevant part that:

- Thoratec described the HeartMate PHP, its design, engineering and component parts.
- Thoratec disclosed to the court all material elements and technical features of the HeartMate PHP.

Dkt. 79-27 at para. 5.

The discrepancy between the declarations is whether the features of the Device that Thoratec attested to as confidential (see section III.A., *supra*) were disclosed in the German court. Weighing Abiomed's previous representations to the Court, the competing declarations and the arguments of counsel at the hearing, this Court does not find Abiomed's proffered statement of its German counsel that "Thoratec disclosed to the court all material elements and technical features of the HeartMate PHP" to be persuasive. Accordingly, the Court is not persuaded that against the backdrop of the facts in this case, Thoratec's presentation of the Device provides grounds to dissolve the Protective Order.

In addition, Abiomed fails to demonstrate how it would be prejudiced if the Device retains its AEO designation for the duration of the German Action, as agreed upon in the Protective Order. It is significant that Abiomed *has the Devices in its possession*, as they were produced in 2019. Dkt. 81-1, para. 4. This is not a situation where Abiomed is moving into the appellate phase of the case without important evidence that it had in hand for the proceeding below. Perhaps consequently, Abiomed's attack on confidentiality is based upon the need for additional persons to have access to the Device. Dkt. 79-21, paras. 2-4; Dkt. 79-26, para. 3. But Abiomed attorneys who were given access to AEO material, including the HeartMate PHP, for purposes of litigating the German Actions still have that access. Further, in meet and confer efforts to resolve this dispute in October 2020, Abiomed provided a list of new individuals for whom it was seeking access to the Device. Dkt. 81-1, para. 6. This list is not limited to Abiomed's counsel but rather comprises Abiomed's entire executive suite. *Id.* Finally, if indeed Abiomed needed modifications to the Protective Order, such as giving different individuals access to AEO material or extending

the date by which AEO material must be returned to Thoratec, Abiomed could have sought to modify the Protective Order. On such a motion, Abiomed typically would have borne the burden of showing good cause. *See CBS Interactive, Inc. v. Etilize, Inc.*, 257 F.R.D. 195, 201 (N.D. Cal. 2009). Abiomed failed to bring such a motion.

IV. CONCLUSION

For the foregoing reasons, the Court concludes that the HeartMate PHP should retain its AEO designation.

SO ORDERED.

Dated: January 28, 2021



SUSAN VAN KEULEN
United States Magistrate Judge